General

Guideline Title

Care of the HIV-infected transgender patient.

Bibliographic Source(s)

New York State Department of Health. Care of the HIV-infected transgender patient. New York (NY): New York State Department of Health; 2012 Jan. 20 p. [17 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Care of the HIV-infected transgender patient. New York (NY): New York State Department of Health; 2011 Jul. 21 p. [18 references]

Recommendations

Major Recommendations

The quality of evidence (I-III) and strength of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

What's New – January 2012 Update

The World Professional Association of Transgender Health (WPATH), formerly known as the Harry Benjamin International Gender Dysphoria Association, has recently updated the *WPATH Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*. Since its first release in 1979, the *WPATH Standards of Care* have been the most recognized standards of care for transgender patients. In addition to updated guidelines on diagnostic assessment, hormone therapy, and surgical therapy, the 7th Version of the *Standards of Care* includes updated information on addressing and promoting tolerance and equality for transgender patients.

Introduction

Clinicians providing services to human immunodeficiency virus (HIV)-infected transgender patients should integrate transgender treatment recommendations and standards of care into their practice. (AII)

Transgender-Related Terminology

Key Point:

Gender identity is distinct from sexual orientation. Sexual orientation involves sexual attraction, whereas gender identity involves the individual's natal sex in relation to the gender that he/she experiences.

Baseline History and Psychosocial Assessment

As part of the routine management of HIV-infected patients, clinicians should perform a psychosocial assessment at baseline and at least annually in HIV-infected transgender patients. (AIII)

See Table 2 in the original guideline document and Mental Health Quick Reference Card for more information (see the "Availability of Companion Documents" field).

Routine Screening and Laboratory Assessments for HIV-Infected Transgender Patients

Routine medical screening of HIV-infected transgender patients should be performed according to standards of care, as determined by clinical judgment and according to the patient's level of comfort. (AIII)

For recommendations on cancer and cardiovascular screening for patients receiving hormone therapy, see "Hormone Therapy" section below.

Table. Strategies to Help Alleviate Patient's Concerns about Physical Examination

- Address the patient's fears
- Explain each step of the examination prior to performing it
- Use the smallest clinically indicated speculum for Pap tests and pelvic examinations
- Use urine-based gonococcal/chlamydial testing for male-to-female patients
- *For extreme cases of anxiety* (particularly in patients with a history of physical or sexual abuse):
  - Consider a referral for psychotherapy to decrease post-traumatic stress-type symptoms prior to physical examination
  - Consider administration of a low-dose anxiolytic prior to physical examination

Pelvic Examination

Clinicians should perform routine pelvic examinations in HIV-infected female-to-male (FtM) patients and male-to-female (MtF) patients who have undergone complete sex reassignment surgery according to HIV care guidelines for natal females. Before performing a pelvic examination in transgender patients, the clinician should explain the medical reasons for the examination. (AIII)

HIV-infected FtM patients remain at risk for gynecologic complications that can be detected by routine pelvic examinations (see the National Guideline Clearinghouse [NGC] summary of the New York State Department of Health [NYSDoH] guideline Primary Care Approach to the HIV-Infected Patient).

Cytologic Screening

Clinicians should perform routine cervical Papanicolaou (Pap) tests in any HIV-infected FtM patient with cervical tissue; patients who are uncomfortable receiving a Pap test should be educated about the importance of obtaining cervical cytology. (AIII)

Clinicians should notify the pathologist when submitting a Pap test sample from an FtM patient who is receiving testosterone therapy because testosterone-related atrophy of the cervix may mimic cervical dysplasia (Grynberg et al., 2010). (AIII)

Anal Pap tests should be performed in HIV-infected transgender patients according to guidelines for natal males and natal females. (AIII)

Neovaginal Pap tests are not indicated for HIV-infected MtF patients. (AIII)

Key Point:

FtM patients receiving testosterone therapy may experience atrophy of the cervix, which can mimic cervical dysplasia (Grynberg et al., 2010). Notifying the pathologist of the patient's testosterone treatment status can increase accuracy of Pap test results.

Screening for Gonococcal and Chlamydial Infections

Clinicians should screen HIV-infected transgender patients at baseline for gonorrhea and chlamydia; screening should also be performed at least annually thereafter for sexually active HIV-infected transgender patients. (AIII)

Clinicians should obtain an accurate sexual history and test all possible sites of exposure when screening for gonorrhea and chlamydia, including the urethra, rectum, and pharynx. (AIII)

For additional information regarding gonococcal and chlamydial infections in HIV-infected patients.

Cross-Gender Therapy for HIV-Infected Transgender Patients

Hormone Therapy

Clinicians should educate HIV-infected transgender patients about the possible health risks associated with hormone therapy. (AIII)

See Table 4 in the original guideline document for information on basic goals and effects of cross-gender hormone therapy.

Concomitant Hormone Therapy and Antiretroviral Therapy (ART)

Hormone therapy for HIV-infected transgender patients who are not initiating or receiving ART should be prescribed according to the same standards of care for all transgender patients. (AIII)

Before prescribing hormone therapy for HIV-infected transgender patients who are receiving ART, clinicians should (AIII):

- Consult with, or refer patients, to a provider who has experience in prescribing both hormone therapy and ART to select appropriate hormone treatment.
- Educate patients about the prescribing considerations, including hormone selection and dose, for optimizing the effects of hormone therapy when prescribed in conjunction with an ART regimen.
- Discuss the importance of adherence to ART with patients, including the risks associated with dangerously high circulating hormone levels due to ART interruption.

Clinicians should monitor hormone therapy in HIV-infected transgender patients according to established guidelines for all transgender patients. (AIII)

Key Point:

Educating patients about how hormone selection and dose can reduce interactions between hormones and ART may encourage acceptance of ART from those who would otherwise decline it.

Key Point:

Cross-gender hormone monitoring for HIV-infected transgender patients is the same as for all transgender patients. Established monitoring guidelines, such as those by the Endocrine Society (Hembree et al., 2009) should be used.

Cancer Screening and Hormone Therapy

Breast Cancer

Clinicians should perform breast cancer screening in the following HIV-infected transgender patients according to clinical judgment and consideration of current guidelines established for natal females of the same age (see Appendix A in the original guideline document):

- FtM patients with remaining breast tissue. (AIII)
- MtF transgender patients with breast tissue who have received hormone therapy for at least 5 years. (AIII)

Prostate Cancer

Clinicians should perform digital rectal examinations as part of routine HIV care for HIV-MtF transgender patients (see the NGC summary of the NYSDoH guideline Primary Care Approach to the HIV-Infected Patient); clinical judgment and current guidelines for natal HIV-infected males should be used when considering prostate examinations in MtF transgender patients (see Appendix A in the original guideline document). (AIII)

Cardiovascular Disease and Hormone Therapy

When HIV-infected transgender patients choose to receive hormones, clinicians should educate them about the cardiovascular effects of hormone therapy and, when indicated, provide counseling to reduce the risk for cardiovascular disease; such discussions should take place at the time of initiation of hormone therapy and frequently thereafter. (AIII)

Gender-Confirming Surgery

The standards of care for gender reassignment surgery, as well as less complicated gender confirming procedures, are the same for HIV-infected transgender patients as for transgender patients who are not infected with HIV. (AIII)

Surgery, including breast implantation and gender-reassignment surgery, is not contraindicated in HIV-infected patients. (AIII)

Mental Health and Substance Use Screening

Clinicians should perform a mental health and substance use assessment in HIV-infected transgender patients at baseline and at least annually thereafter. (AIII)

Clinicians should refer HIV-infected transgender patients requiring mental health services to a psychiatrist or psychologist with knowledge and experience in transgender treatment. (AIII)

If the HIV-infected transgender patient's substance use screening result is positive, or if the patient has a history of substance use, the clinician should re-evaluate the patient's substance use at least quarterly. (AIII)

Clinicians should offer patients with active substance use/abuse problems referral to appropriate substance use treatment programs or other substance use services. (AIII)

For information about mental health and substance use screening, refer to Mental Health Screening: A Quick Reference Guide for HIV Primary Care Clinicians and the NYSDoH guideline Screening and Ongoing Assessment for Substance Use .

Risk- and Harm-Reduction Approach for HIV-Infected Transgender Patients

Clinicians should assess for the following behaviors in HIV-infected transgender patients:

- Silicon use
- Hormones obtained without prescription, including specific hormones used
- Needle-sharing among those who inject hormones, silicone, and/or drugs
- Sexual risk behaviors
- Genital taping

Clinicians should provide risk-reduction counseling and, when appropriate, harm-reduction counseling for HIV-infected transgender patients who report potentially harmful behaviors. Patients at risk for intentionally harming their genitalia require referral for psychiatric evaluation. (AIII)

Case Management for HIV-Infected Transgender Patients

Case managers who provide services to HIV-infected transgender patients should:

- Develop expertise in transgender-related services, such as assisting patients with access to healthcare, assisting with adherence to medical treatment and medical appointments, and making appropriate referrals.
- Closely monitor changes in contact information, housing, and psychosocial support for patients with unstable living situations.
- Develop awareness of "trans-friendly" resources, including education, employment, legal aid resources, and harm-reduction programs.
- Be familiar with the resources available to assist patients with obtaining a change of name and gender status on their identification and health insurance cards. (AIII)

Transgender-Related Standards of Care and Referral Resources

Standards of Care

The most recognized transgender-related standards of care are the World Professional Association for Transgender Health (WPATH) *Standards of Care*, formerly known as the *Harry Benjamin International Gender Dysphoria Association Standards of Care* (www.wpath.org).

The WPATH *Standards of Care* provides a comprehensive description of the "Five Elements of Treatment": 1) diagnostic assessment, 2) psychotherapy, 3) real-life experience, 4) hormone therapy, and 5) surgical therapy. The *Standards of Care* also serve as a resource for related treatment information, including hormonal treatment and surgical options.

Refer to the original guideline document for additional sources of information and referral resources.

Definitions:

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Human immunodeficiency virus (HIV) infection
- Transgender-related conditions

Guideline Category

Counseling

Management

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Allergy and Immunology

Endocrinology

Family Practice

Infectious Diseases

Internal Medicine

Obstetrics and Gynecology

Psychiatry

Psychology

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Public Health Departments

Social Workers

Substance Use Disorders Treatment Providers

Guideline Objective(s)

To provide guidelines for the care of human immunodeficiency virus (HIV)-infected transgender patients

Target Population

Human immunodeficiency virus (HIV)-infected transgender patients

Interventions and Practices Considered

1. Integrating transgender treatment recommendations and standards of care into clinical practice
2. Psychosocial assessment at baseline and at least annually
3. Routine medical screening performed according to standards of care
    - Pelvic examination
    - Cervical and anal Pap tests
    - Screening for gonococcal and chlamydial infections
4. Educating patients about the possible health risks associated with hormone therapy
5. Educating patients about how hormone selection and dose can reduce interactions between hormones and antiretroviral therapy
6. Use of established monitoring guidelines for monitoring cross-gender hormone therapy
7. Breast and prostate cancer screening for those receiving hormone therapy
8. Educating patients about the cardiovascular effects of hormone therapy and, when indicated, providing counseling to reduce the risk for cardiovascular disease
9. Use of standards of care for gender-confirming surgical procedures

10. Mental health and substance use screening
11. Risk-reduction and harm-reduction counseling for patients who report potentially harmful behaviors (e.g., illicit hormone procurement, needle-sharing among those who inject, potentially dangerous forms of physical alteration such as silicone injection and genital taping)
12. Case management that includes expertise in providing transgender-related services and resource referral

Major Outcomes Considered

Adverse effects of cross-gender therapy

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

MEDLINE was searched through December 2010 with use of appropriate key words. Results were limited to publication years 2002-2010. Due to lack of randomized controlled trials on this subject, evidence is limited to small case series, case reports, and expert opinion. Available transgender care guidelines not specifically pertaining to HIV infection were also reviewed, such as the *Principles of Transgender Medicine and Surgery* (Ettner R et al., eds), the World Professional Association for Transgender Health (WPATH) Standards of Care, and transgender guidelines from the British Columbia. Additional information was gleaned from online resources from credible medical websites.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Methods Used to Analyze the Evidence

Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with human immunodeficiency (HIV) infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

*Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Care of Women with HIV Infection
- Committee for the Care of Substance Users with HIV Infection
- Physicians' Prevention Advisory Committee
- Pharmacy Advisory Committee

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Grynberg M, Fanchin R, Dubost G, Colau JC, Bremont-Weil C, Frydman R, Ayoubi JM. Histology of genital tract and breast tissue after long-term testosterone administration in a female-to-male transsexual population. Reprod Biomed Online. 2010 Apr;20(4):553-8. PubMed

Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, Gooren LJ, Meyer WJ III, Spack NP, Tangpricha V, Montori VM, Endocrine Society. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2009 Sep;94(9):3132-54. [157 references] PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate care for the human immunodeficiency virus (HIV)-infected transgender patient

Potential Harms

- *Hormone therapy* may increase the risk for:
  - Cardiovascular disease—particularly venous thromboembolism
  - Certain cancers—including breast, ovarian, and uterine cancers
  - Hepatic complications—due to disturbances in liver metabolism caused by elevated liver enzymes
  - Erectile dysfunction—due to increased circulating estrogen, which may also increase the risk for human immunodeficiency virus (HIV) transmission as a result of condom slippage or reduced condom use
- When hormone adjustments are made because of concomitant antiretroviral therapy (ART), concentrations of circulating hormone can become dangerously high if a patient does not adhere to ART. Severe cardiovascular complications, including stroke, deep vein thrombosis, and pulmonary embolism, may occur.

Qualifying Statements

Qualifying Statements

When formulating guidelines for a disease as complex and fluid as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), it is impossible to anticipate every scenario. It is expected that in specific situations, there will be valid exceptions to the approaches offered in these guidelines and sound reason to deviate from the recommendations provided within.

Implementation of the Guideline

Description of Implementation Strategy

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical

settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDoH) Distribution Center.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

Implementation Tools

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

New York State Department of Health. Care of the HIV-infected transgender patient. New York (NY): New York State Department of Health; 2012 Jan. 20 p. [17 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Jul (revised 2012 Jan)

Guideline Developer(s)

New York State Department of Health - State/Local Government Agency [U.S.]

Source(s) of Funding

New York State Department of Health

Guideline Committee

Committee for the Care of the HIV-Infected Transgender Patient

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Care of the HIV-infected transgender patient. New York (NY): New York State Department of Health; 2011 Jul. 21 p. [18 references]

Guideline Availability

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Availability of Companion Documents

The following are available:

- Mental health screening: a quick reference guide for HIV primary care clinicians. New York (NY): New York State Department of Health. 2012 Jun. Available from the New York State Department of Health AIDS Institute Web site .
- Substance use screening: a quick reference guide for HIV primary care clinicians. New York (NY): New York State Department of Health. 2009 Feb. Available from the New York State Department of Health AIDS Institute Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on January 30, 2012. This NGC summary was updated by ECRI Institute on August 14, 2012.

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